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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,689	09/29/2003	Jan Andersson	06275-131002	1299

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

BUNIN, ANDREW M

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/673,689		ANDERSSON ET AL.	
	Examiner		Art Unit	
	Andrew M. Bunin		3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-41 and 55-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 34-41 and 55-64 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/066,319.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 34-41 and 65-72, drawn to a Dry Powder Inhaler with a means for Removing Powder Residue from a Flow Channel in the reply filed on September 29, 2003 is acknowledged. The applicant has also elected the species of scraper based powder dislodgement. It is also acknowledged that claims 34-41 and 55-64 read on this species, therefore, these claims are considered for examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/066,318 filed on May 8, 1998.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "142" has been used to designate both a "member" and a "supplementary air inlet". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be

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labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR.1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

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- (I) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

It is suggested that the appropriate heading be placed throughout specification as listed above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a scraper, does not reasonably provide enablement for a brush. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the brush in the invention commensurate in scope with these claims. In order for a precise amount of powder to be swept into the dosing means of the invention, a scraper is acceptable over the use of a brush. A brush wouldn't necessarily sweep enough powder to fill the dosing means or could sweep too much powder for the dosing means. In contrast, the scraper is able to accurately scrape the desired amount of powder into the dosing means.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersson et al. (US 6257232). US 6257232 to Andersson et al., applicant describes figures 1-4 as admitted prior art. Given this admission, the following rejection based on 102b is considered appropriate. Figure 1 and 2 disclose a powder inhaler for administering powder by inhalation, comprising a dosing unit 16 for providing a dose of powder and a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is in use drawn on inhalation by a user. One of the surfaces of the flow path is movable relative to at least one other of the surfaces of the flow path. The inhaler further comprises a powder-dislodging member 22, which is of fixed position relative to at least one of the surfaces of the flow path and is configured on relative movement of one and one other of the surfaces of the flow path in order to contact a surface of the flow path such as to dislodge powder accumulated thereon, wherein the powder dislodging member 22 comprises a scraper 40. One of the surfaces of the flow path is movable relative to at least one other of the surfaces of the flow path and the scraper 40 is of fixed position relative to the at least one other of the surfaces of the flow path as shown in figure 2. The flow path includes a chamber 28 includes an inlet and an outlet and at least one of

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the surfaces of the flow path defines art of the chamber 28 as shown in figure 2. In addition, figure 2 discloses at least one of the surfaces of the flow path defining part of opposed surfaces of the chamber 28. Chamber 28 is a storage chamber for storing a plurality of doses of powder and includes a filling inlet in one of the opposed surfaces of the chamber, and a plug for sealing the filling inlet of the storage chamber, which plug includes the scraper. Andersson et al. states, "the top of storage chamber 28 includes an inlet which is closed by a separate plug." (Column 10, lines 34-35) Figure 1 discloses an inhaler comprising a mouthpiece 2, which includes at least one of the surfaces of the flow path.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al. in view of Ambrosio et al. (US 5,829,434). Andersson et al. discloses everything except a housing that includes a screw thread and a cap for covering at least the mouthpiece, where the cap includes a screw thread for engaging the screw thread on the housing. In addition, Andersson et al. also doesn't disclose that the mouthpiece and cap are configured such that at least part of the mouthpiece is rotated relative to the housing on one of screwing or unscrewing the cap where part of the mouthpiece

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remains substantially in a fixed position relative to the housing as the cap is screwed or unscrewed. However, Ambrosio et al. teaches the use of a housing 120 which includes a screw thread 352 and a cap 520 for covering at least the mouthpiece 440, includes a screw thread 520 for engaging the screw thread on the housing as shown in figure 1 and 2. Therefore, it would have been obvious to one of ordinary skill in the art to combine the cap screwing means taught by Ambrosio et al. in combination with the inhaler of Andersson et al. in order to cover the inhaler to keep it isolated from external dirt and other debris.

Ambrosio et al. teaches a cap 520 having ribs 534 and 536 that fall into the recesses 164 and 166 of housing 120. Ambrosio et al. states, "Thus, closing rotation of closure cap 520 causes the same rotation of driving body 120, and thereby of venture conduit 64 relative to metered dose hole 184" (column 24, lines 36-39). Ambrosio et al. discloses the claimed invention except for the mouthpiece and cap are not configured such that at least part of the mouthpiece is rotated relative to the housing on one of screwing or unscrewing the cap where part of the mouthpiece remains substantially in a fixed position relative to the housing as the cap is screwed or unscrewed. It would have been obvious to one of having ordinary skill in the art at the time the invention to place the ribs 534 and 536 at a location level with the mouthpiece and place the recesses on the mouthpiece section 440 of the housing 120, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As for claim 56, Andersson et al. has disclosed at least one other of the surfaces of the flow path as being in a fixed position relative to the housing 6 such that at least

one of the surfaces of the flow path is moved relative to at least one other of the surfaces of the flow path on rotation of part of the mouthpiece 2 relative to the housing 6 as shown figure 3 and 4. The divider 14 in figure 4 allows the mouthpiece 2 to be capable of rotating in the manner stated above.

As for claim 57, Ambrosio et al. teaches a cap 520 having ribs 534 and 536 that fall into the recesses 164 and 166 of housing 120. Ambrosio et al. states, "Thus, closing rotation of closure cap 520 causes the same rotation of driving body 120, and thereby of venture conduit 64 relative to metered dose hole 184" (column 24, lines 36-39). Ambrosio et al. discloses the claimed invention except for the mouthpiece and cap each include parts which engage on the one of screwing or unscrewing the cap so as to rotate part of the mouthpiece relative to the housing. It would have been obvious to one of having ordinary skill in the art at the time the invention to place the ribs 534 and 536 at a location level with the mouthpiece and place the recesses 164 and 166 on the mouthpiece section 440 of the housing 120, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As for claim 58, wherein the engaging parts comprise at least one biased member 534 and at least one recess 164, which at least one biased member 534 is configured to engage at least one recess on the one of screwing or unscrewing the cap 520. Ambrosio et al. states, "due to the resilience of the plastic elements, radially extending ribs 160 of upper securing walls." (column 22, lines 60-62) Therefore, it would have been obvious to one of ordinary skill in the art to use the resilient material of the ribs 160 for ribs 534 and 536.

As for claim 59, see statements for claim 57.

As for claim 60, Andersson et al. discloses a housing 6 that includes a rotatable grip portion 8 that is rotated to provide a dose of powder for inhalation in the same sense as that in which the cap is rotated to rotate the part of the mouthpiece relative to the housing. Andersson et al. states, "the dosing unit 16 is rotated by rotating the grip portion 8 in the counter-clockwise sense...grip portion 8 comprises a resilient member which is configured to engage with an axially-directed surface 60a...so as to rotate the dosing unit 16" (column 2, lines 29-37).

As for claim 61, Ambrosio et al. teaches a rotation resistance mechanism 494 for providing resistance to relative rotation of part of the mouthpiece 440 and the housing 120 as shown in figure 57.

As for claim 62, Ambrosio et al. discusses how the "closing rotation of closure cap 520 causes the same rotation of driving body 120, and thereby venturi conduit 64 relative to metered dose hole 184, to the store position, 180 degrees out of alignment" (column 24, lines 36-39). Therefore, it can be considered obvious that the rotation of the mouthpiece relative to the housing by screwing or unscrewing the cap must be of forces greater than that required to rotate the cap 520.

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al. in view of Ambrosio et al. and further in view of Wetterlin (US 5983893). Ambrosio et al. has disclosed everything except for the rotation mechanism of claim 63 comprising a ratchet mechanism. Wetterlin teaches a ratchet mechanism for an inhalation device in figure 1 and states, "the maneuvering unit 13 is

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rotated...means could be provided as a ratchet mechanism" (column 3, lines 61-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the engaging rotation mechanism taught by Ambrosio et al. with the ratchet mechanism as taught by Wetterlin.

Lastly, it can be considered obvious that the rotation of part of the mouthpiece relative to the housing as taught by Ambrosio et al. would cause no damage thereto. It is considered common sense that an invention would take into consideration that a cap would cause no damage when being screwed or unscrewed. Therefore, it would have been obvious to one of ordinary skill in the art to combine the screwing cap technology taught by Ambrosio et al. with the inhaler disclosed by Andersson et al. in order for the inhaler to be effectively closed off from allowing external dirt or material from entering the inhalation device.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-4, 18, 23, 30, and 39 of U.S. Patent No. 6,257,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because "movable member" is used instead of powder dislodging member. In addition, it states in claim 34 that the powder-dislodging member comprises one of a scraper or a brush, which is not stated in the claims of the patent. However, Patent #6257232 discloses a scraper that reads on the claims pertaining to the movable member. In addition, claim 40 states a plug for sealing the filling inlet of the storage chamber, which is also not stated in the claims of the patent. However, as stated above in the 102b rejection, the applicant has considered the plug common in the related prior art in order to seal a filling inlet of a storage chamber.

Claims 55 and 59-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-4 of U.S. Patent No. 6,446,626 in view of Ambrosio et al. (US 5,829,434). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent don't state a mouthpiece and cap configured such that part of the mouthpiece is rotated relative to the housing on one of screwing or unscrewing the cap. However, this limitation is considered obvious in view of Ambrosio et al. (US 5687710) as discussed in the 103a rejection above.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 4907583, US 4805811, US 4667668, US 6240918, US 5243970, and US 5687710

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AMB
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